

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

ST. JUDE MEDICAL AB
Patent Dept.
S-175 84 Järfälla
SUÈDE

Date of mailing (day/month/year) 13 December 2000 (13.12.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 98 P 2018 P	
International application No. PCT/SE99/01383	International filing date (day/month/year) 17 August 1999 (17.08.99)

1. The following indications appeared on record concerning:	
<input type="checkbox"/> the applicant	<input type="checkbox"/> the inventor
<input type="checkbox"/> the agent	<input checked="" type="checkbox"/> the common representative
Name and Address PACESETTER AB Patent Dept. S-175 84 Järfälla Sweden	State of Nationality
	State of Residence
	Telephone No. +46-8/474-4072
	Facsimile No. +46-8/761-2905
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:	
<input type="checkbox"/> the person	<input checked="" type="checkbox"/> the name
<input type="checkbox"/> the address	<input type="checkbox"/> the nationality
<input type="checkbox"/> the residence	
Name and Address ST. JUDE MEDICAL AB Patent Dept. S-175 84 Järfälla Sweden	State of Nationality
	State of Residence
	Telephone No. +46-8/474-4571
	Facsimile No. +46-8/761-2905
3. Further observations, if necessary:	
4. A copy of this notification has been sent to:	
<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer A. Karkachi
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C.20231
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 17 April 2000 (17.04.00)	Applicant's or agent's file reference 98 P 2018 P
International application No. PCT/SE99/01383	Priority date (day/month/year) 31 August 1998 (31.08.98)
International filing date (day/month/year) 17 August 1999 (17.08.99)	
Applicant BRAND, Paul et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

02 February 2000 (02.02.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Claudio Borton Telephone No.: (41-22) 338.83.38
--	---

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

ST. JUDE MEDICAL AB
Patent Dept.
S-175 84 Järfälla
SUÈDE

Date of mailing (day/month/year) 13 December 2000 (13.12.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 98 P 2018 P	
International application No. PCT/SE99/01383	International filing date (day/month/year) 17 August 1999 (17.08.99)

1. The following indications appeared on record concerning:	
<input checked="" type="checkbox"/> the applicant	<input type="checkbox"/> the inventor
<input type="checkbox"/> the agent	<input type="checkbox"/> the common representative
Name and Address PACESETTER AB S-175 84 Järfälla Sweden	State of Nationality SE
	State of Residence SE
	Telephone No.
	Facsimile No.
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:	
<input type="checkbox"/> the person	<input checked="" type="checkbox"/> the name
<input type="checkbox"/> the address	<input type="checkbox"/> the nationality
<input type="checkbox"/> the residence	
Name and Address ST. JUDE MEDICAL AB S-175 84 Järfälla Sweden	State of Nationality SE
	State of Residence SE
	Telephone No.
	Facsimile No.
3. Further observations, if necessary:	
4. A copy of this notification has been sent to:	
<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer A. Karkachi
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 98 P 2018 P		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE99/01383	International filing date (day/month/year) 17/08/1999	Priority date (day/month/year) 31/08/1998	
International Patent Classification (IPC) or national classification and IPC A61N1/375			
Applicant PACESETTER AB et al.			



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 02/02/2000	Date of completion of this report 13.11.00
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Fischer, O Telephone No. +49 89 2399 2327 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/SE99/01383

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-10 as published

Claims, No.:

1-6 as received on 29/09/2000 with letter of 26/09/2000

Drawings, sheets:

1/2,2/2 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE99/01383

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-6
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: US-A-4 278 093 (Lafortune et al.) 14.07.1981

D2: US-A-4 934 366 (Truex et al.) 19.05.1990

2. Document D1 is regarded as the closest prior art to the subject-matter of claim 1.
- 2.1 As far as claim 1 can be understood (see Item VIII), D1 discloses (col. 2, l. 59 - col. 3, l. 44, figs. 1-2) a pacer housing comprising a connector means adapted to receive a contact plug with "plug contact surfaces" on the proximal end of a lead with an electrode locate on the distal end of said lead (connector assembly 21), said connector means comprising a tubular member having two ends (sleeve 22), said tubular member being located inside said housing (fig.1), said tubular member being bondable to said housing (col. 3, l. 33-36 and fig. 1), said tube being structurally intact along its length (fig.2). Each end of the tube (sleeve 22) can be said to be bonded to corresponding openings in the housing (fig. 1). The interior means (collet 23) contact the "plug contact surfaces" and are per se located within the enclosure formed by the tube.
- 2.1 The subject-matter of claim 1 therefore differs from D1 in that the tube is provided with one or several lateral contact openings and with contact surfaces for establishing the contact to the interior of said housing, said contact surfaces being accessible through said openings, said contact surfaces being electrically connected to contact means for contacting the "plug contact surfaces".

Hence, the subject-matter of claim 1 is new in the sense of Article 33 (2) PCT. Accordingly, the dependent claims are also new (Art. 33 (2) PCT).

- 2.2 The differentiating feature of contacting the contact surfaces through openings is not anticipated nor rendered obvious by D2 either. In fact, in D2, the conductive surfaces

(fig. 1, references 80,84,88) are directly accessible from the outer periphery of the tube. Moreover, three conductive sections are separated by two non-conductive ceramic sections. This implies complex machining of the metallic conductive sections, whereas in the present application the conductive sections are simply metal rings.

In addition, the claimed tube will ensure a high strength of the connective part.

- 2.3 Therefore, it would not be obvious for the skilled person to arrive to the claimed invention in view of the disclosures of D1 and D2. Thus, the subject-matter of claim 1 involves an inventive step in the sense of Article 33 (3) PCT. Accordingly, the dependent claims also meet the requirements of Article 33 (3) PCT.

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in document D1 is not mentioned in the description, nor is this document identified therein.
2. Although claim 1 is drafted in the two-part form the features recited in claim 1 from line 12 (after characterized in that) to the comma of line 20 are incorrectly placed in the characterising portion, as they are disclosed in document D1 in combination with the features placed in the preamble (Rule 6.3(b) PCT) (see also Item V, point 2.1).

Re Item VIII

Certain observations on the international application

1. The expression "contact surfaces" used in claims 1 to 3 designates two different features of the claimed device. On one hand, the expression defines the contact surfaces (111, 118) on the plug (110), and on the other hand it defines the contact surfaces (27, 28) provided in the metal tube (21) for establishing the contact to the interior of the housing.

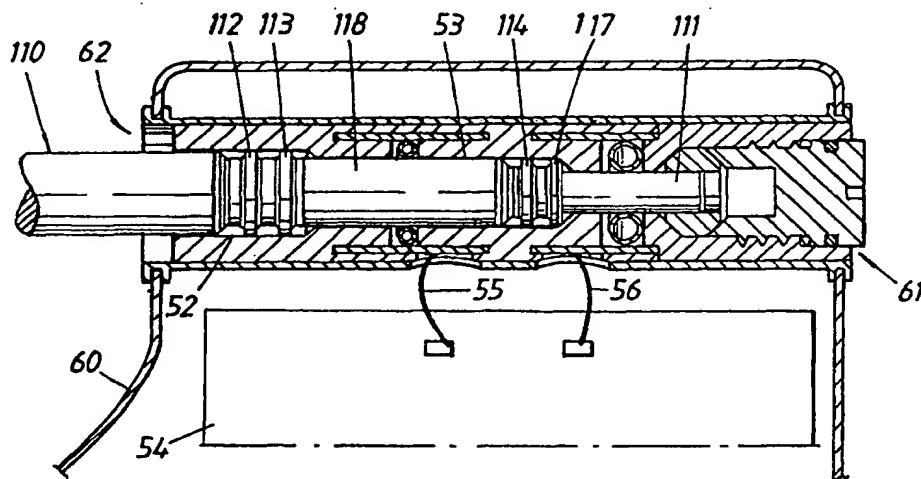
2. Therefore this expression leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of the claims unclear (Article 6 PCT).
3. It would have been preferable to use two different expressions to define both features. For example, the expression "plug contact surfaces (111, 118)" would have met the requirements of Article 6 PCT.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61N 1/375	A1	(11) International Publication Number: WO 00/12174 (43) International Publication Date: 9 March 2000 (09.03.00)
<p>(21) International Application Number: PCT/SE99/01383</p> <p>(22) International Filing Date: 17 August 1999 (17.08.99)</p> <p>(30) Priority Data: 9802928-3 31 August 1998 (31.08.98) SE</p> <p>(71) Applicant (for all designated States except US): PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): BRAND, Paul [SE/SE]; Travarvägen 31, S-175 39 Järfälla (SE). HILL, Rolf [SE/SE]; Gösvägen 8, S-175 55 Järfälla (SE).</p> <p>(74) Common Representative: PACESETTER AB; Patent Dept., S-175 84 Järfälla (SE).</p>		<p>(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: DEVICE IN CONNECTION WITH PACERS



(57) Abstract

The invention relates to a pacemaker housing (60) comprising a connector means adapted to receive a contact plug (110) with contact surfaces (111, 118) on the proximal end of a lead (115) with an electrode located on the distal end of said lead. Said housing is made of metal and said connector means comprises a tubular member (20) having two ends (22, 23), said member (20) being located inside said housing (60). A first end (23) of said tubular member (21) is welded or bonded to a first opening (62) in a wall of said housing (60). Said tubular member (20) comprises a tube (21) made of a metal being weldable or bondable to said metal housing (60). The tube (21) is structurally intact along its entire length and the second end (22) of said tube (21) is welded or bonded to a second opening (61) in said housing (60). All interior means (27, 28, 57, 58) in said tube for contacting the contact surfaces (111, 118) on said plug are thus located within the enclosure formed by said tube (21) of metal.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon	KR	Republic of Korea	PL	Poland		
CN	China	KZ	Kazakhstan	PT	Portugal		
CU	Cuba	LC	Saint Lucia	RO	Romania		
CZ	Czech Republic	LI	Liechtenstein	RU	Russian Federation		
DE	Germany	LK	Sri Lanka	SD	Sudan		
DK	Denmark	LR	Liberia	SE	Sweden		
EE	Estonia			SG	Singapore		

Device in connection with pacersTechnical field of the invention.

The present invention relates to pacer housings and more particularly to those parts of the housing intended for connection to the electrode leads.

Background of the invention.

Implantable pacers normally comprise a pacer housing (also called can) containing electronic circuitry and a unit for electric power as well as different electrodes which are connected to the interior parts in the pacer housing and which are to be implanted in or in the vicinity of the heart. The electrodes are connected to the pacer by means of leads. The internal parts of the pacers have to be well protected against the internal environment, especially the body fluids in the body for a long period of time, which places strict requirements on all entries into the interior of the can and especially on the connections of the leads to the housing. At the same time it should be possible to disconnect the pacer from the implanted leads for replacement or servicing of the pacer. The connective parts of the pacer and the leads have largely been standardized so as to encompass a relatively deep female socket comprising a number of contact surfaces whereas the leads are provided with a male part comprising one or several corresponding peripheral, generally circular contact surfaces.

At present the connective part of the pacer housing containing the female socket is made of a transparent material, normally of epoxy resin, which is molded onto the housing and onto contacts extending outwardly from the housing. The male part of the leads is normally locked by means of set screws, although other fastening means have been envisaged. The positioning and alignment of the different contact surfaces and of the fastening means or metallic threads for the set screws prior to the molding of

the connective part is however complicated and the delay in the manufacturing process incurred by the curing of the epoxy resin is considerable.

- 5 It would thus be desirable if the molding procedure could be dispensed with.

It has been discussed that these complexities could be avoided by designing the pacer with a socket located inside
10 the metal housing. To our knowledge this kind of sockets, sometimes termed "black holes", are not used at present.

US-A-4,934,366 and US-A-5,324,311, both of which are incorporated by reference, describe two interior sockets or
15 black holes for pacers. Both designs comprise a tubular member consisting of a number of longitudinally alternating sections made of metal respectively of insulating ceramics. An end section of metal can be welded or bonded to an opening in the pacer housing by means of a flange. The use
20 of different materials however set high standards in regard of precision and durability of the component parts as well as on the assembly procedure thereof. This is especially important since the interior sockets must meet very high standards regarding the integrity of the interior of the
25 pacer housing during long times of implantation in a demanding environment. The manufacture of these prior art sockets thus is relatively complicated.

Short description of the inventive concept

- 30 According to the invention the molding procedure can be avoided and the design of an interior socket can be simplified to a high degree whilst still meeting the required high standards by designing a pacer housing in accordance with the appended main claim. Preferred
35 embodiments are set forth in the dependent claims.

Short description of the appended drawings

Fig 1 shows a conventional pacemaker housing with a transparent, molded connective part;

5

Fig 2 shows a lead with a male connective part;

Figs 3 - 6 show a preferred embodiment of the connective part in accordance with the present invention;

10

Detailed description of preferred embodiments of the invention.

Fig 1 illustrates a conventional pacemaker housing 1 having a molded, transparent connective part 2. The connective part 2 includes a female socket 3. The inner end of the socket 3 is provided with a longitudinal bore 7 having a relatively small diameter. The bore 7 is provided with a contact surface 4 adjacent to which threads 5 for a set or lock screw are located in a bore 6 oriented orthogonally relative to the female socket. The housing is hermetically sealed also in relation to the molded part 2 and the contact between the interior electronics and the contact surface 4 is achieved by means of a feed-through. The feed-through comprises a ceramic plug, typically made of alumina, into which one or more leads have been soldered. This lead is bonded (e.g. ultrasonically welded) to the electronics and to the contact surface 4. The ceramic plug is soldered or brazed by means of gold into a sleeve made of titanium. This operation may be made at any time before the assembly of the pacemaker housing. The sleeve is welded into an opening in the housing in a sealing manner during the assembly of the pacemaker housing that normally consists of two halves. Before the connective part is molded onto the housing, these halves are welded together and sealed.

Fig 2 illustrates a lead 15 comprising a proximal connecting plug 10 and a distal, transvenous, intracardial electrode 16 as well as an attachment means 17 for suturing the proximal end of the lead in the body of the patient. The connecting plug 10 is designed to be received in the socket 3 and the end thereof is provided with a longitudinally projecting contact pin 11 as well as a cylindrical body 17 provided with sealing rings 12, 13, 14 intended to engage and seal against the corresponding inner cylindrical surface of the female socket 3. The shape of the pin 11 corresponds to the shape of the bore 7. When the plug 10 is inserted into the socket 3 the pin 11 engages the contact surface 4 and the set-screw in the bore 6 can be tightened against the pin 11 in order to securely lock the plug 10 in the socket 3. The complexities involved in holding the bores, contact surfaces and threads in position and keeping them open and free from the molding material during the molding process are evident.

For the sake of simplicity, the above prior art device has been illustrated as being unipolar. A bipolar embodiment naturally will be more complex to manufacture. The preferred embodiments of the invention described below will relate to bipolar embodiments.

Figs 3 - 5 show a preferred embodiment of the invention comprising a tubular member 20. For the sake of clarity, the reference signs not repeated throughout all drawings.

The member comprises a tube 21 with two open ends 22, 23. Each end is to be welded into a respective opening in the pacer housing. The tube is made of the same metal as the pacer housing, in this case titanium. The mid-section of the tube is provided with two relatively small lateral openings 24, 25. The openings 24, 25 are sealed by means of a ceramic plug 26 fitting snugly in the tube and soldered with gold against the inside of the tube. Two contact rings 27, 28 have been molded into the ceramic plug overlapping the

lateral openings. The ceramic plug also originally could consist of several separate parts with the contact rings held between and soldered to these parts, thus uniting the parts of the plug to a unitary unit. The soldered junctions
5 then would form an efficient seal.

It should be noted that the size of the openings 24, 25 being necessary to allow the bonding of the leads to the parts of the contact rings accessible through the openings
10 24, 25 and 31, 32 is small, seen in relation to the entire circumference and to the length of the tube. The openings thus do not affect the structural integrity of the tube. The contact rings 27, 28 moreover overlap the openings and are bonded thereto by means of the intermediate layer of
15 ceramics, in this way strengthening the area in which said openings are located.

Typical dimensions for a tube intended to house a standard IS-1 male connector are for instance an inner diameter of 5
20 mm, a wall thickness of 0.3 mm (i. e. the same as the thickness of typical pacemaker housing walls) and a diameter of the holes 24, 25 of about 2 mm. A minimum area of about 4 mm² is necessary for the equipment presently used for bonding leads to metallic surfaces. The length of the tube
25 is of course adapted to the specific housing into which it is to be placed, but might typically be about 25 mm.

These dimensions of course can be varied as long as the tube remains structurally intact, i. e. as long as the tube has a
30 strength and rigidity that is sufficient to prevent loads, including thermal stresses, on the housing and/or the connector to be transferred as tensile forces to the ceramic parts. Of course, low tensile forces not exceeding the tensile strength of the ceramic could be accepted. Since
35 there are standards regarding the loads a pacemaker housing and connector should be able to withstand and regarding the overall tightness of the housing, variations of the

dimensions only would involve standard stress calculations and dimensioning well within the scope of the man in the art. It should be noted that this also could take the degree of soldering between ceramic plug and tube into account, 5 since this would determine the extent to which tube and ceramic would function as a composite without going outside the ordinary skill of the man skilled in the art.

The ceramic plug is provided with an interior bore 10 corresponding to the shape of the male connector in the same way as the molded prior art female connector described above and thus includes interior sealing surfaces 52, 53 for engagement with the sealing rings on the male connector.

15 A part 30, 31 of the inside of the contact rings is not covered with the ceramic material. In this way two inner circumferential grooves are obtained in the inner bore of the ceramic plug. The bottom of the grooves consists of the metal in the contact rings. Two openings 32, 33 are also 20 provided in the outer surface of the ceramic plug that may be made to coincide with the lateral openings 24, 25 in the tube wall. These openings give access to the contact rings 27, 28 when the ceramic plug has been mounted correctly in the tube 21.

25

Thus, when the ceramic plug 26 has been soldered or bonded into place, the openings 24, 25 will be completely sealed by the plug 26 although allowing electrical connection to the interior of the tube via the contact rings 27, 28.

30

To this extent the tubular member can be manufactured in advance as desired.

Both ends of the prefabricated tube can be welded to the 35 pacer housing and the housing parts can be welded together after the connection of interior leads from the interior electronics to the contact rings, should this be desired.

The remaining parts, i. e. the means achieving the contact between the contact rings and the contact surfaces on the male connector part on the lead and the means locking or fixating the male connector part in the socket, can easily
5 be inserted afterwards. This means for instance that these parts would not interfere with the standard helium-based procedures for testing the housing with connector for leaks or that these parts would not be affected by the leak testing procedure.

10

Fig 3 shows the main component parts of the tubular member, the tube 21 with openings 24, 25, the ceramic plug 26, a fixation part 40 and two circular spring contacts 57, 58. The spring contacts are similar to the spring contacts used
15 in US-A-4,934,366.

The fixation part 40, shown in more detail in Fig 4, is designed in the same way as the lead locking device disclosed in US-A-4,784,141, herewith incorporated by
20 reference, and comprises a hollow cylindrical part 41 fitting into the end of the tube 21. The inner end of the cylindrical part 41 is provided with an interior flange 42 with an inner conical surface 43. The locking device further comprises a resilient locking ring 44 located adjacent the
25 flange 42. One side of the ring has a conical surface 45 that is complementary to the conical surface 43. The other side of the ring also has a conical surface 46 that is complementary to a conical surface 47 on a plug 48 provided with exterior threads 49 fitting into interior threads 50 on
30 the inside of the cylindrical part 41. The outside of the plug 48 is provided with an O-ring 51 that is located in a peripheral groove 52 and sealingly engages the inside of the cylindrical part 41. When the plug 48 is screwed into the cylindrical part 41, the resilient ring 44 will be forced
35 inwards into contact with the contact pin of the male connector part by means of the interaction of the different

conical surfaces, thus locking the contact pin inside the tube.

The tube 21 preferably is of the same material as the pacemaker housing, which normally is made of titanium. The ceramic plug may for instance be made of alumina, Al_2O_3 , and the contact rings may for instance be made of stainless steel or of titanium.

10 In the above embodiment the ceramic plug has been illustrated as extending from the end of the tube and past the openings in the side of the tube. It is however only necessary that the ceramic plug cover the openings. The remaining part can be designed as a separate part inserted
15 and bonded to the tube after the assembly of the pacemaker housing in a similar way as the fixation means.

Fig 4 shows the tube with all component parts mounted.

20 Fig 5 shows how the tube has been mounted in a pacemaker housing 60 and welded to openings 61, 62 in the openings via flanges located on the outside of the tube ends. Fig 5 also shows a male connector plug 110 inserted in the tubular member. The plug has a contact pin 111, a contact surface 118 and four
25 sealing rings 112, 113, 114, 117. The resilient ring 44 grips the pin 111 and the sealing rings 112 - 114, 117 are in engagement with the interior sealing surfaces 52, 53.

The connector means can be achieved in a simple way compared
30 with the prior art molded connector means.

As mentioned above, the ceramic part can be soldered into the tube in advance by similar methods as used when obtaining the feed-through in the prior art. The tube then
35 is placed in the openings in one of the pacemaker housing halves and conductors 55, 56 are bonded (typically by means of ultrasonic welding) to the connecting parts of the

electronic board 54 and to the parts of the contact rings that are accessible via the openings in the tube. The housing halves then are assembled and the two halves and the ends of the tube are welded together by means of a laser beam to form a sealed unit. This unit then is tested for leakage, for instance by means of standard helium-based procedures. It should be noted that no other kinds of work operations than those already used in the prior art are necessary.

10

The pacer then is finished by slipping the resilient spring contacts into the respective interior grooves in the ceramic plug and by inserting and bonding the lead locking means into place in the corresponding open end of the tube.

15

The new connective part thus is very simple to manufacture and to mount in the pacer housing. The welding and sealing of the housing only includes the additional step of welding the ends of the tube to the edges of the openings in the housing, which is done in the same operation as the welding of the two housing halves. After the welding operation, no further operations are necessary, except for the simple insertion of contact rings and lead locking mechanism.

25 Since the tube after the welding operation in principle forms an integral, load-carrying part of the pacer housing, a high degree of tightness and integrity is obtained. The tube will ensure a high strength and a high durability of the connective part, whilst the ceramic plug will ensure a high degree of tightness in view of the large contact area between ceramic plug and tube that can be used for soldering, i.e. sealing.

35 Although a pacer housing with one tubular member has been illustrated, the housing of course can contain several members. The housing also wholly or partly could be made of a non-metallic material as long as the parts in which the

10

openings holding the tube are of metal or of a material allowing a bond of sufficient strength to the metal tube. Furthermore, although the tube has been illustrated as having a circular cross-section, other cross-sections are possible.

One important advantage with the connector according to the invention is that the connecting pin 111 on the end of the lead can be reached from the outside through the end of the tube containing the lead locking means. This will facilitate the removal of the male connector from the female socket since the pin 11 can be pushed outwardly through said second end by means of a tool if the male connector proves to be difficult to pull out. In the above, preferred embodiment it is sufficient to unscrew the threaded plug 48, thus exposing the end of the contact pin 111. Furthermore, in this state a stylet could be introduced into the longitudinal channel, for instance for repositioning the electrode with the aid of the internal electronics in the pacer. The plug 48 could also contain a sealable, longitudinal bore, for instance sealed by a screw, for this purpose.

One important feature of the invention is the possibility of achieving a high capacitance between contact ring and tube by allowing the ceramic plug and one of the contact rings to extend all the way to one end of the tube. Ring and tube will be separated by the ceramic, which is chosen to be insulating and thus is a dielectricum. Connecting a small capacitor between ring and tube can increase the capacitance further.

One important advantage of a high capacitance is that it helps avoid interference.

Claims

1. Pacer housing (60) comprising a connector means adapted to receive a contact plug (110) with contact surfaces (111, 118) on the proximal end of a lead (115) with an electrode located on the distal end of said lead, said housing preferably being made of metal, said connector means comprising a tubular member (20) having two ends (22, 23), said member (20) being located inside said housing (60), a first end (23) of said tubular member (21) being welded or bonded to a first opening (62) in a wall of said housing (60), **characterized** in that said tubular member (20) comprises a tube (21) made of a metal being weldable or bondable to said metal housing (60), said tube (21) being structurally intact along its entire length, the second end (22) of said tube (21) being welded or bonded to a second opening (61) in said housing (60), all interior means (27, 28, 57, 58) in said tube for contacting the contact surfaces (111, 118) on said plug thus being located within the enclosure formed by said tube (21) of metal.

2. Pacer housing according to claim 1, **characterized** in that said metal tube (21) is provided with one or several lateral contact openings (24, 25), contact surfaces (27, 28) for establishing the contact to the interior of said housing being located in said opening(s) (24, 25), said contact surfaces being electrically connected to said means (57, 58) for contacting said contact surfaces (111, 118) on said plug (110).

30

3. Pacer housing according to claim 1 or 2, **characterized** in that said opening(s) (24, 25) are closed by means of one or several insulating ceramic plug(s) (26) fitting into said metal tube, said ceramic plugs being soldered or bonded to said tube, said plugs holding said contact means (27, 28) for contacting the interior of said housing.

35

4. Pacer housing according to claim 3, **characterized** in that said contact means comprise metal rings (27, 28) that are molded or bonded into the ceramic plug(s) (26), the outside of said ceramic plug(s) (26) being provided with openings
5 (32, 33) corresponding to said lateral openings in said tube, thus giving access to said rings from the outside of said tube.

5. Pacer housing according to claim 3 or 4, **characterized** in
10 that the central part of the inside of said metal rings (27, 28) is free from said ceramic, thus providing a peripheral groove (30, 31) at the inside of said rings (27, 28) giving access to said rings from the inside of said tube.

15 7. Pacer housing according to any one of the preceding claims, **characterized** in that lead locking means (40) are located in said second end (22) of said tube (21), means (48) for operating said lead locking means (40) being accessible from said second end (22) of said tube (21).

20

8. Pacer housing according to claim 7, **characterized** in that said lead locking means (40) are removable wholly or partly to give access to said contact plug (110).

1 / 2

Fig. 1

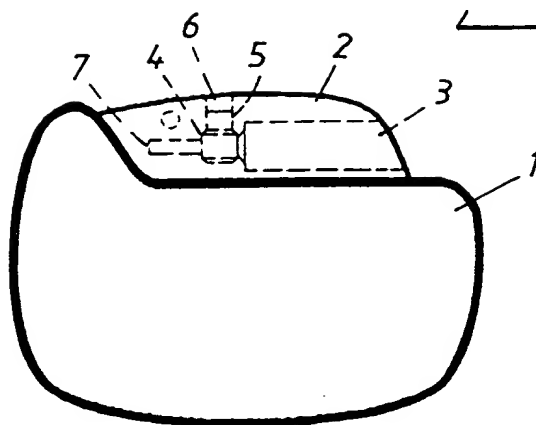
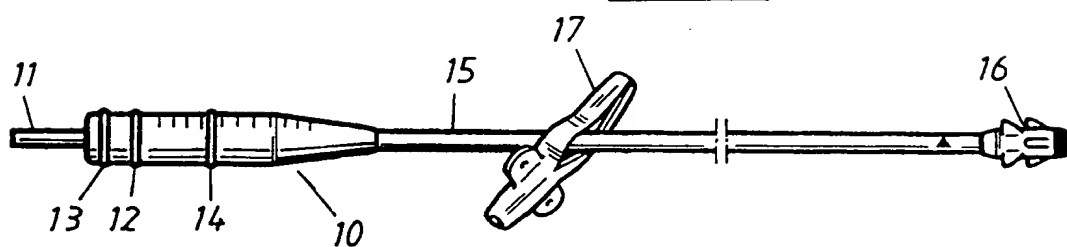


Fig. 2



2 / 2

Fig. 3

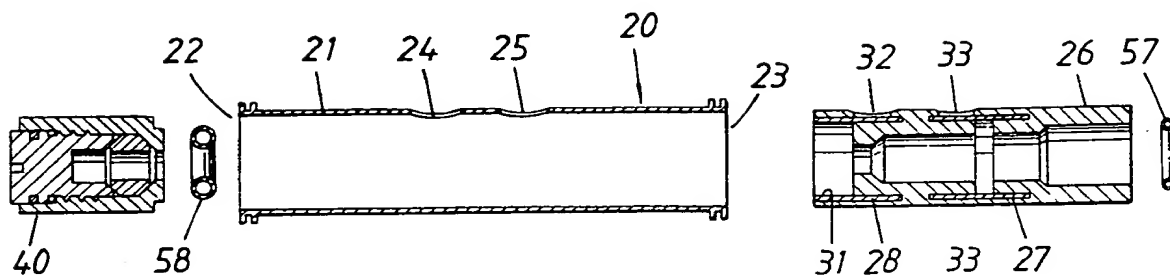


Fig. 4

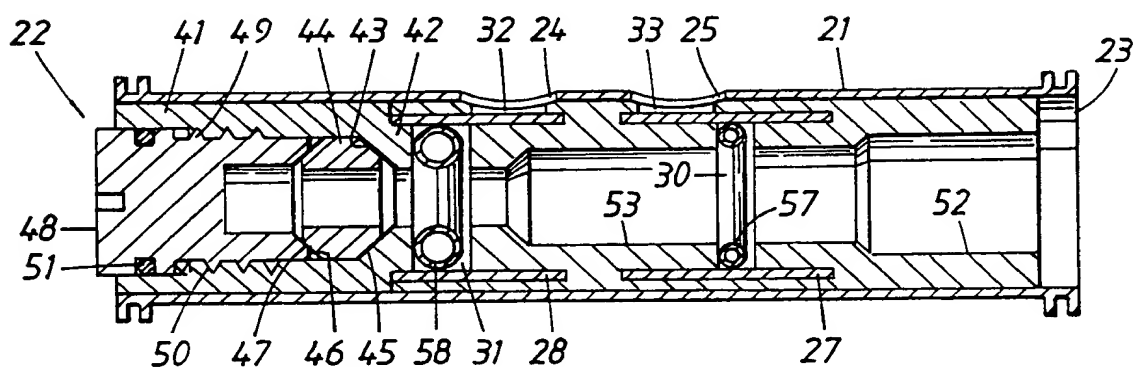
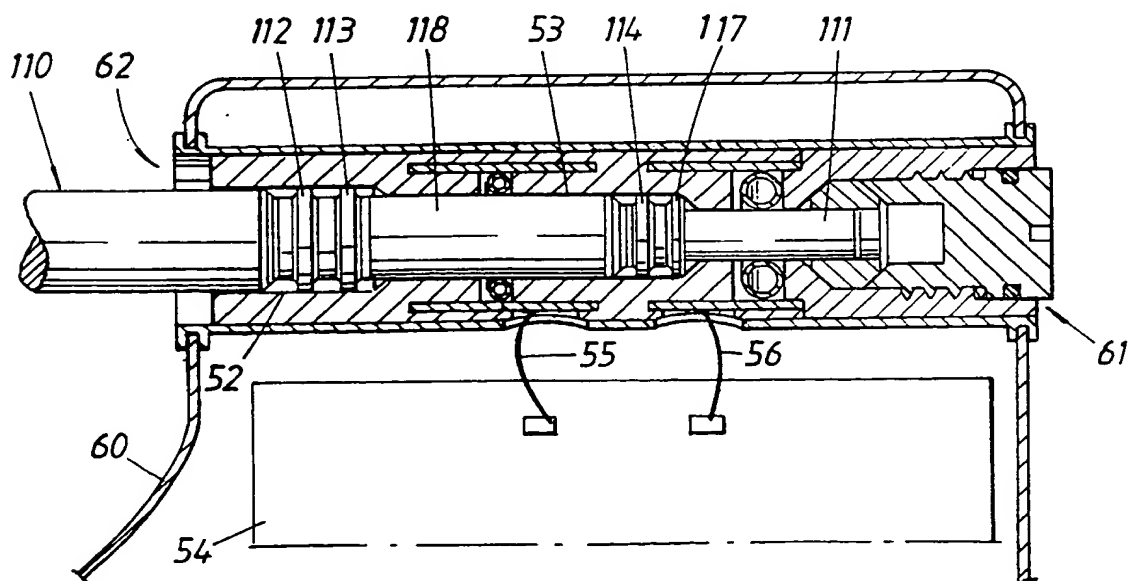


Fig. 5



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01383

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/375

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	US 5843141 A (T.C. BISCHOFF ET AL.), 1 December 1998 (01.12.98) --	1-7
A	US 5545188 A (J.I. BRADSHAW ET AL.), 13 August 1996 (13.08.96), figure 1, abstract --	1-7
A	US 4278093 A (R. LAFORTUNE ET AL.), 14 July 1981 (14.07.81), figure 1, abstract --	1-7
A	EP 0261582 A1 (SIEMENS ELEMA AB), 30 March 1988 (30.03.88), figure 1, abstract --	1-7

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document but published on or after the international filing date	"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search	Date of mailing of the international search report
20 December 1999	
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/AE Telephone No. +46 8 782 25 00

International application No.

PCT/SE 99/01383

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT
Information on patent family members

02/12/99

International application No.
PCT/SE 99/01383

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
US	5843141	A	01/12/98	AU	6557998 A	24/11/98
				WO	9848896 A	05/11/98

US	5545188	A	13/08/96	NONE		

US	4278093	A	14/07/81	NONE		

EP	0261582	A1	30/03/88	DE	3783110 A	28/01/93
				US	4913147 A	03/04/90

US	4934366	A	19/06/90	AU	625115 B	02/07/92
				AU	5175390 A	18/04/91
				DE	69027846 D,T	21/11/96
				EP	0448651 A,B	02/10/91
				JP	4503021 T	04/06/92
				JP	5067312 B	24/09/93
				WO	9104069 A	04/04/91
				AU	611328 B	06/06/91
				AU	4308089 A	02/04/90
				DE	68921744 D,T	23/11/95
				EP	0404877 A,B	02/01/91
				SE	0404877 T3	
				JP	3502656 T	20/06/91
				WO	9002581 A	22/03/90
